

National Cancer Institute  
Institutional Review Board  
**AGENDA (revised 6/4/14)\***  
June 9, 2014  
1:00 – 5:00 pm  
10 CRC/3-1608

- 1. Review of Draft Minutes, May 12, 2014**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Initial Review** P141559, "Transformation of Plexiform Neurofibromas to Malignant Peripheral Nerve Sheath Tumors in Neurofibromatosis Type 1: Clinical, Histopathologic, and Genomic Analysis" - Brigitte Widemann, PI
- 9. Response to Stips** 08C0088G, "Low Intensity Allogeneic Hematopoietic Stem Cell Transplantation Therapy of Metastatic Renal Cell Carcinoma Using Early and Multiple Donor Lymphocyte Infusions Consisting of Sirolimus-Generated Donor Th2 Cells " - Daniel Fowler, PI
- 10. Amendment** 12C0008-D, "An Open Label Phase I Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Maximum Tolerated Dose of the Antimesothelin Antibody Drug Conjugate BAY 94-9343 in Subjects with Advanced Solid Tumors" - Raffit Hassan, PI
- 11. Amendment** 14I0009-B, "Characterization and Management of Patients With HIV-1 Infection Who Experience Virologic Failure Despite Combination Antiretroviral Therapy " - Alice Pau, Pharm.D., PI
- 12. Amendment** 09C0082-S, "Assessment of the Safety and Feasibility of Administering T cells Expressing an anti-CD19 Chimeric Antigen Receptor to Patients with B-cell Lymphoma or Leukemia" - Steve Rosenberg, PI
- 13. Amendment** 10C0166-K, "A Phase II Study Using Short-Term Cultured, Autologous Tumor-Infiltrating Lymphocytes Following a Lymphocyte Depleting Regimen in Metastatic Digestive Tract and Urothelial Cancers" - Steve Rosenberg, PI

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- 14. \*Amendment** 12C01118-E, "A Phase II Study of Sunitinib in Patients with Advanced Relapsed or Refractory Thymoma or Thymic Carcinoma with at Least One Prior Line of Platinum-Based Systemic Chemotherapy" – Arun Rajan, PI
- 15. Initial Review** P141608, "Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies" - Terry Fry, PI
- 16. Initial Review** P141572, "Phase I Trial of the Combination of Bortezomib and Clofarabine in Adults with Refractory Solid Tumors" - Shivaani Kummar, PI
- 17. Initial Review** P121028, "Phase I/II of PCI-32765 (BTK Inhibitor) and Lenalidomide alone followed by DA-EPOCH-R + PCI-32765 and Lenalidomide with Gene Expression Profiling and Mutational Analysis in Relapsed/Refractory ABC subtype Diffuse Large B-cell Lymphoma " - Wyndham Wilson, PI